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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 693,746	10 20 2000	David E. Lowery	6297.1cp-PUJ-0295	7494

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EXAMINER

MURPHY, JOSEPH F

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 01/27/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/693,746

Applicant(s)

LOWERY ET AL.

Examiner

Joseph F Murphy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10/29/2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above claim(s) 1-45, 47-58 and 60-62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 46 and 63 is/are rejected.
- 7) ☒ Claim(s) 59 is/are objected to.
- 8) ☒ Claim(s) 1-63 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Formal Matters***

Claim 59 was amended and new claim 63 was added in Paper No. 12, 10/29/2002.

Claims 1-63 are pending. Claims 1-45, 47-58, 60-62 stand withdrawn from consideration pursuant to 37 CFR 1.142(b). Claims 46, 59, 63 are under consideration.

### ***Response to Amendment***

The rejections of claim 59 under 35 USC § 112 first paragraph have been obviated by Applicant's amendment, and are thus withdrawn.

The rejection of claim 59 under 35 USC § 112 second paragraph for recitation of the term "represented by" has been obviated by Applicant's amendment, and is thus withdrawn.

### ***Claim Rejections - 35 USC § 112 first paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 46 stands rejected, and new claim 63 is rejected, under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for identifying a compound capable of modulating binding between SEQ ID NO: 157 and SEQ ID NO: 22, does not reasonably provide enablement for a method for identifying a compound capable of modulating binding between a DmGPCR and a DmGPCR binding partner, or DmGPCR9 and SEQ ID NO: 157, or a method for identifying a compound capable of modulating binding between a DmGPCR having 95% identity to SEQ ID NO: 22 and a binding partner having a sequence 95% identical to SEQ ID NO: 157. The specification does not enable any person

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skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Claims 46 and 63 are overly broad in the recitation of DmGPCR, DmGPCR9, and a DmGPCR binding partner, and a DmGPCR having 95% identity to SEQ ID NO: 22 and a binding partner having a sequence 95% identical to SEQ ID NO: 157. The specification discloses that the term DmGPCR embraces species homologs (page 18, lines 19-27), fragments of the full length polypeptide (page 19, lines 17-21), and allelic variants (page 19, lines 4-7). Insufficient guidance is provided as to which of the myriad of polypeptide species encompassed by the claim will retain the characteristics of a DmGPCR, a DmGPCR9 or a DmGPCR binding partner. Applicants do not disclose any actual or prophetic examples on expected performance parameters of any of the possible muteins of a DmGPCR, a DmGPCR9 or a DmGPCR binding partner. It is known in the art that even single amino acid changes or differences in the amino acid sequence of a protein can have dramatic effects on the protein's function. It is also known in the art that a single amino acid change in a protein's sequence can drastically affect the structure of the protein and the architecture of an entire cell. For example, Voet et al. (1990) teaches that a single Glu to Val substitution in the beta subunit of hemoglobin causes the hemoglobin molecules to associate with one another in such a manner that, in homozygous individuals, erythrocytes are altered from their normal discoid shape and assume the sickle shape characteristic of sickle-cell anemia, causing hemolytic anemia and blood flow blockages (pages 126-128, section 6-3A and page 230, column 2, first paragraph).

Since the terms DmGPCR, DmGPCR9 or DmGPCR binding partner encompasses species homologs (page 18, lines 19-27), fragments of the full length polypeptide (page 19, lines

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17-21), and allelic variants (page 19, lines 4-7), and a DmGPCR having 95% identity to SEQ ID NO: 22 and a binding partner having a sequence 95% identical to SEQ ID NO: 157 encompasses muteins, and given the art recognized unpredictability of the effect of mutations on protein function, it would require undue experimentation to practice the claimed method. See *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404. The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. The factors considered to be relevant in the instant case are set forth below:

(1) the breadth of the claims - The claims are drawn to a method for identifying a compound capable of modulating a species homologs, fragments of the full length polypeptide, and allelic variants of a DmGPCR, a DmGPCR9 or a DmGPCR binding partner, or a method for identifying a compound capable of modulating binding between a DmGPCR having 95% identity to SEQ ID NO: 22 and a binding partner having a sequence 95% identical to SEQ ID NO: 157.

(2) the nature of the invention - The instant invention is a method of compound identification.

(3) the state of the prior art - The Voet reference demonstrates that even single amino acid changes or differences in the amino acid sequence of a protein can have dramatic effects on the protein's function.

(5) the level of predictability in the art - The Voet reference demonstrates the unpredictability of the protein art.

(6) the amount of direction provided by the inventor - Applicant has only taught a method for identifying a compound capable of modulating binding between SEQ ID NO: 157 and SEQ

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ID NO: 22, not methods for identifying a compound capable of modulating a species homologs, fragments of the full length polypeptide, and allelic variants of a DmGPCR, a DmGPCR9 or a DmGPCR binding partner or a DmGPCR having 95% identity to SEQ ID NO: 22 and a binding partner having a sequence 95% identical to SEQ ID NO: 157.

(7) the existence of working examples - Working examples are not provided for methods for identifying a compound capable of modulating a species homologs, fragments of the full length polypeptide, and allelic variants of a DmGPCR, a DmGPCR9 or a DmGPCR binding partner or a DmGPCR having 95% identity to SEQ ID NO: 22 and a binding partner having a sequence 95% identical to SEQ ID NO: 157.

(8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. Given the breadth of claims 46 and 63 in light of the predictability of the art as determined by the number of working examples, the level of skill of the artisan, and the guidance provided in the instant specification and the prior art of record, it would require undue experimentation for one of ordinary skill in the art to practice the claimed invention.

Applicant argues that they are not required to provide a Specification that demonstrates the activity of every species encompassed by the claims, even in an unpredictable art, and that the experimentation to demonstrate whether a putative modulator decrease or increase binding would not be undue. However, in *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991), the court ruled that a claim to a large genus of possible genetic sequences encoding a protein with a particular function that needs to be determined subsequent to the construction of the genetic sequences may not find sufficient support under 35 USC 112, 1st paragraph, if only a few of the sequences that meet the functional limitations of the claim are

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disclosed and if undue experimentation would be required of one skilled in the art for determining other genetic sequences embraced by the claim. In the instant case there are a large number of amino acid sequences which are 95% identical to SEQ ID NO: 22 and 157, however these sequences are various unrelated proteins. Therefore, while the specification provides the necessary guidance to make the amino acid sequences set forth in SEQ ID NO: 22 and 157, it does not provide the necessary guidance for one of skill in the art to use the amino acid sequences which are not DmGPCR's. Furthermore, since no functional language is associated with the amino acid sequence 95% identical to SEQ ID NO: 157 and 22, one of ordinary skill in the art would not know how to use these defined sequences except in further characterization of the sequences themselves.

Claims 46 stands rejected, and new claim 63 is rejected, under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

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These are genus claims. According to the specification, the term DmGPCR embraces species homologs (page 18, lines 19-27), fragments of the full length polypeptide (page 19, lines 17-21), and allelic variants (page 19, lines 4-7) and a DmGPCR having 95% identity to SEQ ID NO: 22 and a binding partner having a sequence 95% identical to SEQ ID NO: 157 encompasses muteins. The specification and claims do not indicate what distinguishing attributes shared by the members of the genus. The specification and claim do not place any limit on the number of amino acid substitutions, deletions, insertions and/or additions that may be made to SEQ ID NO: 22 and SEQ ID NO: 157. Thus, the scope of the claim includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Although the specification states that these types of changes are routinely done in the art, the specification and claim do not provide any guidance as to what changes should be made. Structural features that could distinguish compounds in the genus from others in the protein class are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, SEQ ID NO: 157 and SEQ ID NO: 22 are insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.



Applicant argues that the Specification provides adequate written description because the specification describes preferred modifications to the polypeptides, and also provides assays with which one of skill in the art may test such modifications.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between structure and function structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. In the instant case, there is no functional language associated with the amino acid sequence 95% identical to SEQ ID NO: 157 and 22, and additionally, there is insufficient direction in the specification that correlates the variant structure encompassed by the claims to any function.

***Claim Rejections - 35 USC § 112 second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 46 stands rejected, and new claim 63 is rejected, under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 46 and 63 are vague and indefinite in the recitation of the terms "DmGPCR", and "DmGPCR9". There is no definition within the claim to define the protein to which these acronyms refer. Thus, the metes and bounds of this claim cannot be determined.

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Applicant argues that the term "DmGPCR" is defined in the specification. However, although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

### ***Conclusion***

Claims 46 and 63 are rejected.

Claim 59 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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*Advisory Information*

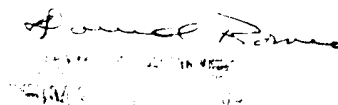
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245. The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Joseph F. Murphy, Ph. D.  
Patent Examiner  
Art Unit 1646  
January 21, 2003



Daniel R. Jones  
Patent Examiner  
Art Unit 1646